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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,381	11/14/2003	Marc C. Albertsen	0578RC-US	1318
7590	10/21/2005			
Patricia A. Sweeney 1835 Pleasant St. West Des Moines, IA 50264				
EXAMINER IBRAHIM, MEDINA AHMED				
ART UNIT		PAPER NUMBER		
1638				

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,381

Applicant(s)

ALBERTSEN ET AL.

Examiner

Medina A. Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 23-42 are pending and are examined.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56. Parent application 09/504, 487 is not listed in the Oath.

Sequence Listing

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and amino acid sequences set forth in 37 CFR 1.821 (a)(1) and (a) (2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. The CRF and paper sequence listings of 11/14/03 have been entered. However, the sequences of on page 9, lines 10-11 have no SEQ ID NO: and the sequences on Figure 8 have not been identified by SEQ ID NO: in the Brief Description of the Drawings on page 8 of the specification. Applicant is respectfully requested to identify the sequence presented in the figures and in the specification or to submit a new Sequence Listing which comprises said sequences. Applicant is also required to amend the specification to recite SEQ ID NO: for said sequences.

Claim Objections

At claim 27, it is suggested that a comma be inserted before "wherein", for formality.

At claim 40, it is suggested that ---isolated regulatory--- be inserted before "nucleotide", for proper dependency.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 24-26, as written, do not sufficiently distinguish over regulatory sequences that exist naturally in maize because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" as in claims 23 and 32. See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 33-37, and 36, 40 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30 and 33 are indefinite because "a nucleotide sequence the prevents the development of plant male tissues" is not clearly defined in the specification. The nucleotide sequence is subject to individual interpretations. Therefore, the metes and bounds of the claims are unclear. While clarification is required, new matter should be avoided. Dependent claims 34-37 are included in the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-42 are rejected under 35 U.S.C. 112, **first paragraph**, because the specification, while being enabling for the isolated regulatory sequence of SEQ ID NO: 1 or 2, an expression cassette comprising said sequence, expression vector comprising said expression cassette, plants and plant cells transformed with said expression vector, and a method of transforming plant/cell with said vector, does not reasonably provide enablement for the specific regulatory regions of from 1 to 1311, or 1155 to 1311, or 1179 to 1208, or 1239 to 1278 of SEQ ID NO: 1 or 2 or any fragment thereof having regulatory activity. The specification does not enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to an isolated regulator nucleotide sequence from base 1 to base 1311, or 1155 to 1311, or 1179 to 1208, or 1239 to 1278 of SEQ ID NO: 1 or 2 or any fragment thereof having regulatory activity, expression cassettes/vectors comprising said regulatory sequence, plants and plant cells transformed with said vectors, and methods of transforming plants/cells with said vectors. In contrast, Applicant teaches SEQ ID NO: 1 and 2, and methods of transforming plants/cells with said regulator sequences.

Applicant has not provided guidance for the sequences of claims 23-26 and 32 having male tissue specific promoter activity or methods for their use for the production of transgenic plants with altered fertility. No regions necessary for regulatory activity have been disclosed or evaluated for these sequences. Applicant has not provided guidance as to what modifications would allow the disclosed sequences to retain their regulatory activity, so as heterologous genes can be expressed to provide male sterility/fertility trait in transgenic plants. In addition, No transgenic plant with altered gene expression or altered phenotype as a result of expressing said promoter fragments have been disclosed.

The state of the art teaches unpredictability inherent in promoters to function either constitutively or tissue-specifically when one or more nucleotide bases of the promoter are modified. For example, Kim et al (Plant Molecular Biology, 1994 vol. 24, pp. 105-117) teach the extreme sensitivity of promoter regions to single base pair

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changes, the absolute requirement for as few as 3 to 6 nucleotides for promoter function, and the failure of a promoter to function either constitutively or specifically when lacking oligonucleotide regions approximately 100 bp upstream of the transcription start site (page 106, paragraph bridging the columns; paragraph bridging pages 107 and 108; page 110, paragraph bridging the columns). Benfey et al (Science, 1990, vol. 250, pages 959-966) teach tissue specificity of fragments of the CaMV 35S promoter can vary depending on the location of the fragment within a promoter (Figure 1, page 960). In addition, the claimed hybridizing sequences, and sequences having 75% sequence identity would comprise non- functional transcriptional, translational, elements, i.e. modifications to highly conserved promoter regions such as CAAT, and TATA elements, required for proper expression of genes, may be rendered inactive by said modifications. Therefore, the ability of the claimed polynucleotides to function as promoter is uncertain.

While Applicant is not required to exemplify each and every claimed embodiment, specific guidance is required with respect to which region of the disclosed sequences can be modified so that the male-tissue specific regulatory activity is retained. Absent such guidance, one skilled in the art would not be able to make the sequences of claims 23-26 and 32, without undue experimentation.

Therefore, given the lack of guidance as discussed supra; the unpredictability inherent in the function of a promoter when lacking specific regions necessary for regulatory activity, the breadth of the claims; and state of the art, the claimed invention is not enabled.

See *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991), where it is taught that the disclosure of a single gene sequence did not enable claims broadly drawn to any analog thereof.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32, 38-39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Cigan et al (US 5, 795, 753).

Cigan et al teach an isolated anther-specific promoter of 5126 gene from maize operably linked to a nucleic acid encoding a product that inhibits pollen formation, transformed maize plants and seed comprising said genetic construct, and a method for producing male sterile plant by expressing said construct in a transgenic plant. The reference also teaches breeding the transformed with another plant of the same species. Given the broad interpretations of "a fragment", the 5126 gene promoter from maize would inherently comprise a fragment of Applicant's SEQ ID NO: 1 or 2, absent evidence to the contrary. Therefore, Cigan teaches all claim limitations.

Remarks

The polynucleotide sequence of SEQ ID NO: 1, 2 and specific regions thereof as recited in the claims are deemed free from prior art of record.

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No claim is allowed.

Contact Information

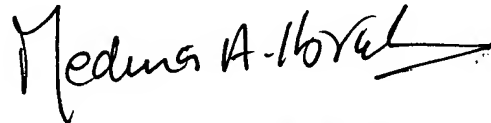
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/27/05

Mai



**MEDINA A. IBRAHIM
PATENT EXAMINER**